EXHIBIT L

RLL-200.1US

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: CHANDRAN *et al.*

Examiner: Rebecca Cook

Application No.: 09/923,491

Group Art Unit: 1614

Filing Date: August 7, 2001

For: LIQUID FORMULATION OF METFORMIN

SECOND PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicants respectfully request that the following amendments be entered.

In the Specification:

Please amend page 1, line 3 as follows:

This application is a continuation of United States Patent Application Serial No. 09/923,491, now issued as United States Patent No. 6,599,187, and is claiming the benefit of United States Provisional Application Serial No. 60/223,391, filed on August 7, 2000.

RANBAXY

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DATE: June 18 2003 #OF PAGES: 14 (INCLUDING THIS COVER)

TO: Examiner Rebecca Cook
(703) 308-4556

FROM: Kim Campbell, IP Dept.

Re: U.S. Application No.: ~~09/923,491~~ 10/382,442
Applicant: CHANDRAN *et al.*
Filing Date: August 7, 2001
Title: LIQUID FORMULATION OF METFORMIN
Group Art Unit: 1614
Our Ref.: RLL-200US

Dear Examiner Cook,

Please see attached Second Preliminary Amendment regarding the above matter.

If you require further information, please do not hesitate to contact me.

Very truly yours,

Kim Campbell
Patent legal assistant

Att.

In the claims:

Please amend claims 1, 3, and 7, delete claim 6 and add claims 51-63 to read as follows:

1. (Currently Amended): A liquid pharmaceutical composition for oral administration ~~to a subject in need thereof~~ which comprises a therapeutically effective amount of metformin or its pharmaceutically acceptable salt; ~~thereof and pharmaceutically acceptable liquid~~ carrier a sweetener that does not increase the blood glucose level of a subject after ingestion thereof; a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight; a mineral acid and bicarbonate salt both present in sufficient amounts to maintain the pH of the composition in the range of about 4.0 to about 9.0; and a pharmaceutically acceptable liquid carrier.

3. (Currently Amended): The liquid pharmaceutical composition according to claim 1 comprising a therapeutically effective amount of the pharmaceutically acceptable salt metformin ~~in association with~~ and a pharmaceutically acceptable liquid carrier.

6. (Cancelled): The liquid pharmaceutical composition according to claim1 which additionally comprises a sweetener that does not increase the blood glucose level of a subject after ingestion thereof.

7. (Currently Amended): The liquid pharmaceutical composition according to claim 1 which additionally comprises ~~a sweetener that does not increase~~

the blood glucose level of a subject after ingestion thereof, an alkyl hydroxyethylcellulose, or a polyhydroxy alcohol, or combination thereof.

51. (New): The pharmaceutical composition of claim 1 wherein the sweetener is present in amounts ranging from about 50% to about 70% by weight.

52. (New): The liquid pharmaceutical composition of claim 51, wherein the sweetener is present in amounts ranging from about 55% to about 65% by weight.

53. (New): The liquid pharmaceutical composition of claim 7, wherein the alkyl hydroxyethylcellulose is present in amounts ranging from about 0.05% to about 1% by weight.

54. (New): The liquid pharmaceutical composition of claim 53, wherein the alkyl hydroxyethylcellulose is present in amounts ranging from 0.08% to about 0.2% by weight.

55. (New): The liquid pharmaceutical composition of claim 1, wherein the polyhydroxy alcohol is present in amounts ranging from about 15% to about 40% by weight.

56. (New): The liquid pharmaceutical composition of claim 7, wherein the alkyl group in alkyl hydroxy ethyl cellulose contains 2 to 10 carbon atoms.

57. (New): The liquid pharmaceutical composition of claim 1, wherein the sweetener is a sugar alcohol or non-nutritive sweetener.

58. (New): The liquid pharmaceutical composition of claim 1, wherein the polyhydroxy alcohol contains 2 to 6 carbon atoms and contains 2 to 6 hydroxy groups.

59. (New): The liquid pharmaceutical composition of claim 1, wherein the polyhydroxy alcohol is a polymer having a molecular weight ranging from 200 to 2000 daltons and has a repeating unit of 2 to 6 carbon atoms and the repeating unit contains 2 to 6 hydroxy groups.

60. (New): The liquid pharmaceutical composition according to claim 1 wherein the mineral acid is hydrochloric acid, nitric acid, or sulfuric acid.

61. (New): The liquid pharmaceutical composition according to claim 60 wherein the mineral acid is hydrochloric acid.

62. (New): The liquid pharmaceutical composition according to claim 1 wherein the pH ranges from about 4.2 to about 7.0.

63. (New): The liquid pharmaceutical composition according to claim 1 wherein the bicarbonate salt is potassium bicarbonate.

REMARKS

Claims 1-7, 32, 42, 43 and 51-63 are currently pending. Claim 1 has been amended by reciting polyhydroxy alcohol present in amounts of from about 15% to about 55%, and calling for mineral acid bicarbonate. Support for amended claim 1 is found in applicant's specification as filed, for example, on page 11, lines 3-6, page 15, lines 11-19, and page 5, lines 6-12. Support for new claims 51-63 is found in dependent claims as filed in the parent to this continuation application. No new matter is introduced thereby.

Entry of this Second Preliminary Amendment is respectfully requested in order to correct this application, and further to define the claims to be examined in this application.

Respectfully submitted,

Chandran *et al.*

By: _____

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